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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,305	10/06/2000	Michael W. Kaiser	FORS-04447	5698
72960	7590	05/09/2011		
Casimir Jones, S.C. 2275 DEMING WAY, SUITE 310 MIDDLETON, WI 53562			EXAMINER	
			STAPLES, MARK	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/684,305	Applicant(s) KAISER ET AL.	
	Examiner MARK STAPLES	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-108 is/are pending in the application.
- 4a) Of the above claim(s) 65-81 and 98-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53,56-64,82-95 and 106-108 is/are rejected.
- 7) ☒ Claim(s) 54,55,96 and 97 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/03/2011 and 03/03/2011</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice of Comply</u> . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of species of the *Archaeoglobus fulgidus* endonuclease having the sequence of SEQ ID NO: 179 of Group A and *Thermus aquaticus* DNA polymerase of Group B in the reply filed on 04/01/2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 65-81 and 98-105 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/01/2011.

It is noted that claims 65, 90, and 102 and listed dependent claims are withdrawn as they do not read on an elected species. It is especially noted that the "chimerical" FEN-1 endonuclease is not elected and SEQ ID NO: 179 is not a sequence of a chimeric FEN-1 endonuclease.

In summary, claims 53-64, 82-97, and 106-108 as filed on 04/01/2011 and consonant with species elections will be fully examined for patentability.

Drawings

2. The drawings are objected to because Figures 13-15, 19-21, 23, 30, 32, 41, 60, 65, 67, 70-A, 71, 85, 87, 89, and 107 respectively contain sequences without SEQ ID NOs (see Sequence Compliance below). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

This objection can be overcome by Applicant identifying sequences by sequence identifiers (“SEQ ID NO:X”) included in a Sequence Listing either: (1) in the drawings or (2) in the Brief Description of the Drawings” (see MPEP § 2422.02).

Sequence Rules Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given time of reply to this office action within which to comply with the sequence rules, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in **abandonment** of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Figures 13-15, 19-21, 23, 30, 32, 41, 60, 65, 67, 70-A, 71, 85, 87, 89, and 107 respectively contain sequences without SEQ ID NOs. If these sequences are included in the sequence listing provide by Applicant, the specification should be amended to include the SEQ ID NOs. If these sequences were not included in a filed sequence

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listing, Applicant should provide a substitute sequence listing and a CRF that include those sequences.

Specification

4. The first sentence of the specification should be updated to reflect that this application is a Divisional of U.S. patent application No. 08/878,653 filed 29 November 1996 issued as U.S. Patent No. 5,843,669 on 01 December 1998 and of U.S. patent Application No. 08/758,314 filed 02 December 1996.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect that the claims are directed to methods using an archaeal FEN-1 endonuclease.

6. The use of the trademark TWEEN® has been noted in this application. It and any other trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 53, 56-64, 72-75, 77-95, and 106-108 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No.5,843,669. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims recite methods using the species FEN-1 endonuclease which is *Methoanococcus jannaschii* (Mja) FEN-1 endonuclease (and see Title) with a second structure polymerase which render obvious the genus methods of the instant claims.

9. Given the large number of related cases, Applicant is requested to comply with 37 CFR 1.56 by identification of related copending applications and providing a copy of the current version of claims pending in the those applications that are particularly close to issuance, which raise double patenting issues.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 53, 56-64, 82, 83, 85-95, and 106-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (June 11, 1996), Thompson et al. (1988), and Zhang et al. (1992).

The claims are directed to processes using archaeal endonucleases to cleave nucleic acids. There are no pending product claims.

Regarding claims 53, 56, 60-62, 82, 85-90, 106, and 107 Wu et al. teach methods for treating nucleic acid, comprising: a) providing:

- i) a purified FEN-1 endonuclease (see 2nd paragraph on p. 2042); and
- ii) a single stranded DNA nucleic acid substrate (see Abstract and 2nd paragraph on p. 2042) which single strand from double stranded DNA can be created by the endonuclease tracking along a single-strand DNA branch/oligonucleotide which is not hybridized and thus is not complementary to the target nucleic acid (see Abstract) , or where with use of PCNA a double stranded DNA may be used (see Abstract);
- b) treating said nucleic acid substrate under conditions such that said substrate forms one or more cleavage structures (see 2nd paragraph on p. 2042); and
- c) reacting said endonuclease with said cleavage structures so that one or more cleavage products are produced (see 2nd paragraph on p. 2042).

Regarding claim 53, Wu et al. do not specifically teach an archeal FEN-1 endonuclease.

Regarding claims 56-58 and 92-94, Wu et al. teach use of polymerase thermostable at the temperature of cleavage (see 2nd paragraph on p. 2042) including eukaryotic polymerases (see Abstract) and *E coli* polymerases (see last sentence on p. 2019).

Further regarding claims 56-58 and 92-94, that *Thermus aquaticus* DNA polymerase was well known in the prior art for use with endonuclease is found in the methods and applications of Bej et al. (see section 2 on p. 302 and first full paragraph on p. 305).

Regarding claim 63, Wu et al. teach the double strand melts (see legend to Figure 7) that is, denatures due to temperature.

Regarding claim 64 and 91, Wu et al. detecting cleaved products (see Figure 8). It is noted that the method of Wu et al. is repeatable can generate second cleavage products. Repetition of a process is routine.

Regarding claims 53, 95 Thompson et al. teach archeal FEN-1 endonucleases from *Halobacterium volcannii* (see Title).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of cleaving nucleic acids using eukaryotic endonucleasases of Wu et al. to substitute an archeal FEN-1 endonucleases from *Halobacterium volcannii* for the eukaryotic endonuclease as suggested by Thompson et al. with a reasonable expectation of success. The motivation to do so is provided by Thompson et al. who teach: “Cleavage of the phosphodiester bonds occurred in a manner analogous to that observed for the eukaryotic tRNA intron endonuclease . . .” (see last full paragraph on p. 17954). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Regarding claim 108, Zhang et al. teach methods of cleaving DNA with endonucleases from solid supports (see Abstract and Figures).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of endonuclease cleavage of DNA of Wu et al. and Thompson et al. by cleaving the DNA with an endonuclease from a solid support as suggested by Zhang et al. with a reasonable expectation of success. The motivation to do so is provided by Zhang et al. who teach the use of the solid support permits convenient removal of reagents and catalysts (see Abstract). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Allowable Subject Matter

13. Claims 54, 55, 96, and 97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: no prior art was found which teaches or renders obvious the *Archaeoglobus fulgidus* FEN-1 endonuclease having SEQ ID NO: 179.

15. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Staples/
Primary Examiner, Art Unit 1637
May 5, 2011